

K050641

APR 7 2005

1.4 510(k) Summary of Safety and Effectiveness

Submitted by: Elizabeth J. Mason
Sr. Regulatory Affairs Specialist

Address: Nobel Biocare USA LLC
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Date of Submission: March 11, 2005

Classification Name: Endosseous Dental Implant (21 CFR 872.3640)

Trade or Proprietary
or Model Name: Zygoma TiUnite®

Legally Marketed Devices: Brånemark System® Zygomaticus (K970499)

Device Description:

Zygoma TiUnite® is a titanium endosseous implant longer than traditional endosseous implants. The Zygoma TiUnite® implant is intended to extend through the maxillary sinus and into the Zygoma bone.

Nobel Biocare's Zygoma TiUnite® is manufactured with a significant design modification. This modification is a surface treatment consisting of a titanium oxide layer (TiUnite®) over the implant threads.

Indications for Use:

Nobel Biocare's Zygoma TiUnite® is a titanium endosseous implant with components intended to be placed in the upper jaw arch to provide support for prosthetic devices such as artificial teeth in order to restore the patient's chewing function.

Nobel Biocare's Zygoma TiUnite® includes endosseous implants, a cover screw, healing abutments, and multi-unit abutments.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

APR 7 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Elizabeth J. Mason
Senior Regulatory Affairs Specialist
Nobel Biocare USA LLC
22715 Savi Ranch Parkway
Yorba Linda, California 92887

Re: K050641
Trade/Device Name: Zygoma TiUnite®
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: II
Product Code: NHA
Dated: March 11, 2005
Received: March 14, 2005

Dear Ms. Mason:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

1.3

Indications for Use

510(k) Number (if known): K050641

Device Name: Zygoma TiUnite®

Indications For Use:

Nobel Biocare's Zygoma TiUnite® is a titanium, endosseous implant with components intended to be placed in the upper jaw arch to provide support for prosthetic devices such as artificial teeth in order to restore patient esthetics and chewing function.

Nobel Biocare's Zygoma TiUnite® includes endosseous implants, a cover screw, healing abutments, and multi-unit abutments.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runza
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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